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1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3  
4 IN RE: NEW ENGLAND : MDL No. 2419

5 COMPOUNDING PHARMACY, INC. : Docket No.:

6 PRODUCTS LIABILITY LITIGATION: 1:13-md-2419(RWZ)

7 -----:

8 This document relates to: :

9 : :

10 ARNETTA, ET AL v. BOX HILL :

11 SURGERY CENTER, LLC, ET AL : DEPOSITION OF  
DAVID MAINE, M.D.

12 No. 1:14-cv-14022-RWZ :

13 : :

14 BOWMAN, ET AL v. BOX HILL :

15 SURGERY CENTER, LLC, ET AL :

16 No. 1:14-cv-14028-RWZ :

17 : :

18 DAVIS, ET AL v. BOX HILL :

19 SURGERY CENTER, LLC, ET AL :

20 No. 1:14-cv-14033-RWZ :

21 : :

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1 DREISCH, ET AL v. BOX HILL :

2 SURGERY CENTER, LLC, ET AL :

3 No. 1:14-cv-14029-RWZ :

4 :

5 FARTHING, ET AL v. BOX HILL :

6 SURGERY CENTER, LLC, ET AL :

7 No. 1:14-cv-14036-RWZ :

8 :

9 KASHI, ET AL v. BOX HILL :

10 SURGERY CENTER, LLC, ET AL :

11 No. 1:14-cv-14026-RWZ :

12 :

13 TORBECK, ET AL v. BOX HILL :

14 SURGERY CENTER, LLC, ET AL :

15 No. 1:14-cv-14023-RWZ :

16 :

17 HANDY, ET AL v. BOX HILL :

18 SURGERY CENTER, LLC, ET AL :

19 No. 1:14-cv-14019-RWZ :

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1                   Deposition of DAVID MAINE, M.D., was  
2   taken on Wednesday, March 8, 2017, commencing at  
3   4:36 p.m., at Mercy Medical Center, 435 St. Paul  
4   Place, 4th Floor, Baltimore, Maryland, before  
5   MICHELE D. LAMBIE, Notary Public.

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11   ALSO PRESENT;   Ashley E. Geno, Esquire  
12                   (via telephone)  
13   Reported By:  
14                   Michele D. Lambie, CSR-RPR  
15  
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17  
18  
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21

1 country and Mayo and Beth Israel and Mass General  
2 and Emory, not having done this inspection, that  
3 information was provided to you by Mr. Kirby? You  
4 didn't get that on your own?

5 A. Right. It was discussed with Mr. Kirby.

6 Q. And you didn't -- I mean, you took him at  
7 his word, obviously. You didn't go out and  
8 research that to see if he was accurate?

9 A. That's correct. I did see the Brigham  
10 one, and that's what prompted some conversation.

11 Q. Doctor, if you could turn to page 9. You  
12 cite in the third paragraph, you say, I have  
13 reviewed the materials cited by the plaintiffs as  
14 evidence of pre-outbreak reporting on the dangers  
15 of compounded medications, and then a list of  
16 every, every one of those publications is detailed  
17 without me reading it into the record.

18 A. Um-hum.

19 Q. Is it your testimony you read each and  
20 every one of those?

21 A. I read a lot of them. I mean, these

1 were -- these were provided to me, and I read or  
2 skimmed all of them, but I can't -- it was a  
3 long -- this was -- it was over a year ago. I  
4 don't think I -- I think I -- I don't recall the  
5 YouTube video, but --

6 Q. In 2012, did you have an understanding  
7 that compounding pharmacies, whether they were  
8 required or not required to report adverse events  
9 to the FDA?

10 A. I don't think I thought about it  
11 specifically, but I think -- I didn't think about  
12 it specifically.

13 Q. What's your knowledge base today?

14 A. I think they are.

15 Q. Do you recall specifically reading the  
16 article, the second one that's listed, Potential  
17 Risks of Pharmacy Compounding?

18 A. I don't remember specifically, no.

19 Q. Let me ask you, There's a statement  
20 that's made in here, Unlike FDA approved products,  
21 consumers and prescribers cannot assume that

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1 compounded drugs were made by validated processes  
2 in properly calibrated and cleaned equipment and  
3 that the ingredients in the drug were obtained from  
4 FDA approved sources. Do you agree with that?

5 MR. KIRBY: Hold on a second. Where are  
6 you reading that from?

7 MR. MILLER: The article that's listed,  
8 The Special Risk of Pharmacy Compounding.

9 MR. KIRBY: Do you have a date on it?

10 MR. MILLER: The page is page 3.

11 MR. KIRBY: I'm sorry, the date?

12 MR. MILLER: Oh.

13 MR. COREN: May 31, 2007 corresponds to  
14 prior marked Exhibit 1358.

15 THE WITNESS: May I see it?

16 BY MR. MILLER:

17 Q. Sure.

18 (Document tendered.)

19 MR. COREN: You have one over there.

20 MR. KIRBY: Can you show him where you're  
21 referring?

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1 MR. MILLER: Page 3.

2 MR. KIRBY: It was not marked previously,  
3 was it?

4 THE WITNESS: This is from -- this is  
5 from 2013, from Drug, the journal Drug.

6 BY MR. MILLER:

7 Q. Yes.

8 A. A current opinion. So -- and what page  
9 are you on?

10 Q. Page 3.

11 A. Page 3.

12 Q. Left column.

13 A. Page 3, sorry.

14 Q. Second paragraph, footnote. Go down  
15 where it says, Unlike FDA approved products.

16 A. Show me where you are.

17 Q. Right here (indicating).

18 A. Okay. I was not on the same paragraph.

19 Q. Sorry.

20 (Whereupon, there was a pause for  
21 document examination.)

1 THE WITNESS: Yeah. So, you know, I  
2 don't have an opinion on this. I mean, this is an  
3 article -- this is an opinion article that's  
4 targeting, I assume, pharmacists or pharmacy  
5 students and not really targeting physicians. So  
6 this is, you know, seems like a reasonable opinion,  
7 but not one that I can comment on specifically.

8 BY MR. MILLER:

9 Q. Can you -- you would agree with me,  
10 wouldn't you, that the labeling of compounded  
11 preparations is neither FDA regulated nor  
12 standardized?

13 MR. KIRBY: Objection to form.

14 THE WITNESS: The labeling of compounded  
15 medications is not FDA regulated or standardized?

16 BY MR. MILLER:

17 Q. Yes.

18 MR. KIRBY: Are we talking 2012 or 2016  
19 or 2017?

20 MR. MILLER: 2012.

21 THE WITNESS: I, I don't have an idea.



1 MR. COREN: I apologize.

2 (Whereupon, there was a pause for  
3 document examination.)

4 BY MR. COREN:

5 Q. Dr. Maine, I have given you copy of  
6 what's been previously marked at an earlier  
7 deposition as Exhibit 1356. It is the December 13,  
8 2000 MMWR, and it's one of the documents that are  
9 listed in your report, okay?

10 A. Um-hum.

11 Q. As one of the documents that were out,  
12 that were available, okay?

13 A. (Nodding head yes.)

14 Q. Do you recall seeing this report in  
15 connection with rendering your opinions?

16 A. I don't recall specifically.

17 Q. If we look here, it's the Center For  
18 Disease Control and Prevention, the CDC, and you  
19 would agree with me that's a pretty authoritative  
20 body in the United States?

21 MR. KIRBY: Objection. You can answer.

1 Q. I could destroy the English language.

2 But this is -- basically, we're talking about,  
3 amongst other things, ESIs?

4 A. Correct.

5 Q. And the first case report indicates that  
6 there was a woman, age 77, if we drop down to the  
7 last, the last full sentence on that first column,  
8 it says, The patient's condition continued to  
9 deteriorate, and she died 51 days after her  
10 hospitalization. So we have a death here, correct?

11 A. Correct.

12 Q. If we go to the continuation of the  
13 paragraph at the top, the last sentence says, The  
14 injectable methyl, methylprednisolone had been  
15 prepared by a compounding pharmacy in South  
16 Carolina?

17 A. Um-hum.

18 Q. So we have a death here, right?

19 A. Yes, we have a death.

20 Q. How come the bells didn't ring within  
21 your profession in 2002?

1 MR. KIRBY: Objection.

2 THE WITNESS: So I didn't read this in  
3 2002. Certainly, getting the MMWR, that was not  
4 part of our common practice. I trained, you know,  
5 at a great institution, and we certainly did not  
6 talk about this in our morning rounds or our  
7 morning conferences, and we didn't have the CDC  
8 MMWR really ever presented to us.

9 And in several years thereafter when  
10 Dr. Bhambhani was making her decision with NECC, in  
11 addition to her experience, there were no such  
12 occurrences with NECC of this magnitude that she  
13 was aware of.

14 So, you know, I think this is, this is  
15 certainly concerning when reading it, but I don't  
16 think it was readily available to providers as  
17 common form, commonplace. It's not the New England  
18 Journal of Medicine.

19 BY MR. COREN:

20 Q. And if we look at -- it's page 1112 of  
21 the MMWR.

1 A. 1112?

2 Q. Yes.

3 A. Yes, the last page?

4 Q. Right.

5 A. Yes.

6 Q. Above the references for this particular  
7 section, some health system pharmacists might not  
8 realize they are purchasing injectables prepared  
9 through compounding. Purchasers of pharmaceuticals  
10 should determine if supplies are provided by a  
11 compounding pharmacy that is licensed in their  
12 state and follows appropriate measures to ensure  
13 that injectable products are free of contamination.

14 Isn't the CDC saying, Look, Hey, if  
15 you're going to be ordering these drugs from  
16 compounding pharmacies, you have to do something a  
17 little bit more than just accept?

18 MR. KIRBY: Objection.

19 THE WITNESS: Yeah, I mean, I think, I  
20 think this article suggests that, you know, they  
21 don't have to do the same reporting as

1 pharmaceutical manufacturing.

2 BY MR. COREN:

3 Q. Now --

4 (Whereupon, Maine Deposition Exhibit  
5 Number 1626-8, Article, marked for identification.)

6 BY MR. COREN:

7 Q. Doctor, I apologize for the quality of  
8 that particular copy, but this -- I'm only -- I'm  
9 going to walk us through this. I'm not going to  
10 have to do the whole thing, but what was it,  
11 1626-8, is a copy of an article authored by Lucy  
12 Wilson, David Blythe and Joshua Sharfstein.

13 Do any of those names sound familiar to  
14 you, by any chance?

15 A. Dr. Sharfstein.

16 Q. And Dr. Sharfstein you recognize used to  
17 be --

18 A. The Health Commissioner.

19 Q. Yes. He was Health Commissioner of this  
20 state --

21 A. In Baltimore City.